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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/497,422	02/03/2000	Stephen A. Berry	ARC2914R1	7482

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[REDACTED] EXAMINER

FUBARA, BLESSING M

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1615

DATE MAILED: 07/08/2002

28

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/497,422	BERRY ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 01 April 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1 and 3-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,3-7,12-14,19,20,22,24-26 and 39-45 is/are rejected.
- 7) Claim(s) 8-11, 15-18, 21-23, 27-32 and 34-38 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time and amendment B filed 02/20/02, and amendment C filed 04/01/02. Claims 1, and 3-45 are pending.

Claim Rejections - 35 USC § 112

1. The rejection of claims 1 and 3-42 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn because the claims have been amended to overcome the issues raised in the last office action.

Claim Rejections - 35 USC § 102

2. Claims 1, 3-7, 12-14, 19, 20, 24-26, 33, 39-42 and new claims 43-45 remain rejected under 35 U.S.C. 102(b) as being anticipated by Clark et al. (US 5,374,620).

Applicants argue that the bulk of the teaching of Clark deal with aqueous formulations and the application is directed to non-aqueous vehicles and formulations. Applicants also state that Clark does not refer to viscous single-phase non-aqueous vehicle.

3. Applicant's arguments filed 04/01/02 have been fully considered but they are not persuasive.

Clark teaches non-aqueous vehicles even if the bulk of the teaching is to aqueous formulations. The claims broadly recite "stable non-aqueous single phase biocompatible vehicle comprising two components selected from the group consisting of solvent, surfactant and polymer, wherein the two components are not the same, and wherein the viscosity of the vehicle is between 1,000 and 10,000,000 poise." Any combination of two components selected from

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the group consisting of solvent, surfactant and polymer would inherently be single phase, non-aqueous and have the recited viscosity because there are no further limitations in the claims that would ensure that the viscosities fall within the range recited.

4. Claims 1, 3-7, 12-14, 19, 20, 24-26, 33, 39-42 and new claims 43-45 remain rejected under 35 U.S.C. 102(b) as being anticipated by Sparks et al. (US 4,952,402).

Applicants argue that Sparks does not teach the non-aqueous single-phase vehicle of applicants and does not disclose viscosity of the polymer.

5. Applicant's arguments filed 0401/02 have been fully considered but they are not persuasive.

Applicants claim a broad composition comprising active ingredient and two components selected from the group consisting of surfactant, polymer and solvent wherein the two groups are not the same. The prior art discloses a composition comprising an active agent, a solvent and a polymer and the vehicle of Sparks would inherently have the recited viscosities and would be single phase. Any combination of two components selected from the group consisting of solvent, surfactant and polymer would inherently be single phase, non-aqueous and have the recited viscosity because there are no further limitations in the claims that would ensure that the viscosities fall within the range recited.

6. Claims 8-11, 15-18, 21-23, 27-32 and 34-38 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara
June 28, 2002


THURMAN K. PAGE
SUPERVISOR, PATENT EXAMINER
TECHNOLOGY CENTER 1600